

**WASHINGTON STATE BOARD OF PHARMACY  
MEETING  
October 27, 2006**

Washington State University  
Academic Center, Room 147  
600 North Riverpoint Blvd  
Spokane WA 99210-1495

**CONVENE**

Chair Asaad Awan convened the meeting at 9:06 a.m. on October 27, 2006.

Board Members present:

Donna Dockter, RPh  
Gary Harris, RPh  
Rebecca Hille, Vice-Chair  
Rosemarie Duffy, RN  
Susan Teil-Boyer, RPh  
George Roe, RPh

Staff Members present:

Joyce Roper, Assistant Attorney General  
Lisa Salmi, Acting Executive Director  
Tim Fuller, Pharmacy Consultant  
Andy Mecca, Pharmacy Consultant  
Grace Cheung, Chief Investigator  
Bill Kristin, Pharmacist Investigator  
Doreen Beebe, Program Manager

**October 27, 2006**

**Open Meeting**

**CONSENT AGENDA**

- 1.1** Pharmacist License Application Approval
  - Joshua Nutting – Nuclear Pharmacist
  - Scott Craig – Nuclear Pharmacist
- 1.2** Pharmacy & Other Firm Application Approval
  - New and Closed Firms 08/03/2006 through 09/13/2006
- 1.4** Pharmacy Tech Training Program Approval
  - Yoke's Pharmacy
  - Propac Pharmacy
  - Hanie Castro – Philippine Women's University
  - Kristy Green – The Bryman School of Tempe
  - Hefeng Huang – Fujian College of Public Health
- 1.5** Collaborative Drug Therapy Agreement Acceptance
  - Dan Kent – Vytarin
  - Dan Kent – Diabetes

**1.6 Automated Drug Dispensing Device Acceptance**

- Klickitat Valley Hospital

**1.8 Board Minute Approval**

- August 31, 2006

Items 1.3 – Pharmacy Technician Application Approval; 1.7 Sample Distribution Requests were deleted from the consent agenda. **MOTION:** Rebecca Hill moved to approve 1.1, 1.2, 1.4, 1.5, 1.6 and 1.8. George Roe second. **MOTION CARRIED 6-0.**

**REPORTS**

Acting Executive Director

Lisa Salmi reported:

- The Department of Health held the Annual Board, Commission and Committee (BBC) conference on August 28, 29 and was attended by Rebecca Hille and Gary Harris.
- Initiative 900 mandates that the State Auditor review and analyze the economy, effectiveness and efficiency of state agencies' operations. The Department of Health, Health Professions Quality Assurance will be the first program to under go the audit. The Auditor's office contracted with Clifton Gunderson, a firm from Austin, Texas. The audit is expected to be completed May 2007. The audit will focus on the Department's compliance with existing performance measures.
- The Department has submitted decision packages to the Office of Financial Management for the 07-09 budget. The Department is asking for additional spending authority to reduce the 574 disciplinary case backlog, Attorney General Services, and completion of the new licensing system (ILRS).
- The legislature directed the Department to conduct a criminal background feasibility study. The study is due in December and will examine whether the Department should query additional sources upon receipt of applications and if background checks should be conducted on credential renewals. Currently, the Department queries the Washington State Patrol, National Practitioner Database, and the Health Integrity Protection Database.
- The Board has received one application for the Central Washington Investigator position. Staff will be working with the Human Resources Office to expand recruitment efforts.
- George Roe, Grace Cheung and Lisa Salmi attended the National Association of Boards of Pharmacy (NABP) District VII and VIII (Washington, Arizona, California, Idaho, Montana, Nevada, New Mexico, Oregon, Utah and Wyoming) meeting in Anaheim, California. Program presentations included creating an ethics program for pharmacists, pharmacy practice in long-term care facilities, Medicare prescription drug benefits program, internship/externship experience, Food & Drug Administration update on Prescription Drug Marketing Act, Drug Enforcement Agency update and disaster/emergency preparedness.
- District VII and VIII voted to send a resolution to NABP asking the association to work with DEA and FDA to develop a public education campaign to education consumers about the dangers of ordering drugs through the Internet.
- Staff has devoted a considerable amount of time to prepare rule making documents for the Pharmacist's Professional Responsibilities issue.

Board Members

*Rebecca Hille* reported on a presentation on *Ethics in Government* at the BCC conference, which provided an overview of the ethic laws and an opportunity for discussions and exercises on how the ethic laws apply to a variety of scenarios.

In addition, there was a discussion on the Uniformed Disciplinary Act, responsibilities of Boards and Commissions, and the lawsuit that initiated changes in the disciplinary process.

The conference included a viewing of the July 12, 2006, Department's Government Management Accountability & Performance (GMAP) presentation to Governor Gregoire on Health Professions' Oversight and Discipline.

*Gary Harris* reported that the BCC conference provided an opportunity to discuss differences in authorizing investigations, decision processes and the diversity in the number of disciplinary cases handled by Boards and Commissions represented at the conference.

*George Roe* reported that he participated in the task force charged with reviewing disciplinary and investigative processes.

*Donna Dockter* reported that she was chosen to participate in a pilot project on Continual Professional Development. The University of Washington and the University of Wisconsin have received money for a pilot tasked with looking at improving/enhancing professional practice verse continuing education requirement. The first meeting is scheduled for November 5<sup>th</sup>.

*Susan Teil-Boyer* reported on an emergency preparedness drill that will be taking place on November 14<sup>th</sup> from 3 to 8 p.m. in Pierce County – *Operation Tremor* (large magnitude earthquake drill). The drill will involve hospitals and Emergency Medical Systems (EMS) in the county.

#### Pharmacist Consultants/Investigators

*Tim Fuller* reported:

- Summarized activities related to recent survey conducted to gather input on the Pharmacist's Professional Responsibilities proposed rule.
- Briefed the Board on discussion on the potential for approving electronic transmission of Schedule II prescriptions with the use and verification of digital certificates.
- Updated the Board on emergency response activities resulting from federal and state funds. The funds will provide an opportunity for state and local health districts to purchase antiviral drugs and storage challenges.

*Andy Mecca* reported:

- Presented to attendees of the BCC conference on illegible prescriptions. The presentation focused on several of the recommendations resulting from the Department of Health 2000 Medication Error Report. The report's primary recommendation was to eliminate all handwritten prescription by 2005.
- Participated with representatives from the Department of Labor and Industries, Department of Social and Health Services and the Health Care Authority at a public meeting on October 23<sup>rd</sup> discussing Opioid dosing guidelines developed by the Agency Medical Directors Group.

- Training changes are being implemented for Nuclear Pharmacist to comply with didactic and experiential training requirements developed by the State Radiation Control Agency.
- Mr. Mecca briefed the Board on the DEA's new program Control Substance Ordering System (CSOS) will allows pharmacists to order C2's electronically.

#### Chief Investigator

Grace Cheung reported:

- Investigation and Inspection statistics for August and September.
- August 2006
  - Investigator Jim Lewis provided an overview of Pharmacy Law Relevant to the Role of Pharmacy Technicians in the Pharmacy Inspection Process to the Clark College Pharmacy Technician class.
  - Investigator Richard Morrison provided a presentation to the staff at Jefferson General Hospital on Drug Diversion Detection and Responsibilities.

September

- Board member Rosemarie Duffy attended the quarterly Investigator's meeting.
- Investigator Morrison participated in the MPJE Review Committee Meeting where they reviewed and revised law questions for appropriateness in preparation of the state specific MPJE review in January 2007.
- Investigator Cheung attended a DEA presentation entitled *The Changing Landscape of Prescription Drug Abuse*. Several panels provided updates on current trend and challenges in controlled substance diversions.
- Investigator Cheung attended the Pacific Rim Meth Summit. Updates on methamphetamine action teams from across the country and presentations on other meth related topics.

October

- Investigator Cheung attended the National Association of State Controlled Substances Authorities (NASCSA) meeting. Updates on topics relating to controlled substances, Prescription Monitoring Programs, Buprenorphine, drug disposal and others.
- Rebecca Hille will attend the next quarterly Investigator's Meeting scheduled for December.

### **DISCUSSION**

#### Update on Methamphetamine Workgroup

The Methamphetamine workgroup held its 2<sup>nd</sup> meeting October 18<sup>th</sup>. Board Investigator Jim Doll will lead the Workgroup following Randy Flett's retirement. The Board is represented by Donna Dockter.

Highlights:

- Representatives from the Snohomish County Meth taskforce and Pierce County taskforce presented information on their respective activities to combat methamphetamine in their respective communities.
- Snohomish County has personnel dedicated to review logs and entering the information into a database. They feel the logs appear to be working as a deterrent to purchases made for illegal purposes. The Pierce County taskforce reports that the log has not deterred these activities.
- Presentation by two vendors of electronic transaction logs both offering real-time point of sale technology. Concerns regarding mandating use of electronic logs include ease of

integration within pharmacy computer systems and potential financial impacts to small shopkeepers.

- Discussed pros & cons of making pseudoephedrine products prescription only.

The next meeting of the Workforce is scheduled for January 17, 2007. Representatives from Oregon will discuss their experiences and outcomes in making pseudoephedrine a legend drug.

#### Pharmacist's Professional Responsibilities WAC 246-863-095

Chair Awan restated the decision made at the August meeting regarding Pharmacist's Professional Responsibilities proposed rule amendments and asked to open the proposal for further discussion.

**MOTION:** Gary Harris moved that the Board reconsider the motion from the August 31<sup>st</sup> meeting in order to discuss new information. Rebecca Hille 2<sup>nd</sup>. **MOTION CARRIED.** 6-0

Susan Teil-Boyer offered alternative language developed by representatives of the Washington State Pharmacy Association, Northwest Women's Law Center and Planned Parenthood and supported by Governor Gregoire. The alternative language addresses concerns raised regarding pharmacist versus pharmacy's duty to dispense". **MOTION:** Susan Teil-Boyer moved to approve the new language and proceed with filing a CR102. George Roe 2<sup>nd</sup>. **MOTION CARRIED** 5-0, Donna Dockter abstained.

#### Discussion:

The Board discussed the differences between deliver verses dispense and reviewed the definitions in statute.

RCW 18.64. "Deliver" defined as the actual constructive or attempt to transfer from one person to another of a drug or device whether or not there is an agency relationship.

RCW 18.64. "Dispense" defined as the interpretation of a prescription or order for a drug... and pursuant to that prescription or order the proper selection, measuring, compounding, labeling or packaging necessary to prepare that prescription for delivery.

Donna Dockter expressed concerns that the use of the word "deliver" is unclear and that the assumption is that dispense includes counseling and giving the medication to the patient. Ms. Dockter felt that the word "deliver" is not consistent with the way the Board has written rules in the past. In addition, she stated the practice detailed in 3(c) of the draft establishes a level of service that is unfunded and unreasonable.

Gary Harris felt that 3(c) meets the intent of the rule by minimizing barriers for patient access.

The Board discussed at length the need to hold additional stakeholder meetings or solicit written public comments on the draft language regarding pharmacies. Donna Dockter supported additional stakeholder meetings. Other members felt that the previous stakeholder meetings and large number of written comments had contributed to these changes. There will be additional opportunities to comment after filing the CR102. Additional stakeholder meetings would delay the rules process well into the 2007 Legislative Session.

Joyce Roper clarified that the Administrative Procedures Act (APA) does not require the Board to go back to interested parties and hold additional stakeholder meetings or solicit written comments once the Board has developed language as a result of stakeholder work.

**MOTION:** Rosemarie Duffy moved to proceed and file a CR101 (Preproposal Statement of Inquiry) regarding WAC 246-869 Pharmacies' Responsibilities with a written comment submission process. Gary Harris second. **MOTION CARRIED.** Vote 5-1. Donna Dockter opposed.

Next Steps:

- File CR101 (Public Notice) to open draft WAC 246-869 (Pharmacies) language for written public comments.
- Discuss comments – Board decides whether to proceed with CR102.
- CR102, Small Economic Business Impact Statement and Significant Analysis prepared/filed.
- Public Comment Period.
- Rules Hearing (projected hearing date – March 2007).

## **PRESENTATIONS**

### Wal-Mart/Sam's Club - request for approval of Will-Call Kiosk.

Tim Fuller provided a brief introduction to the request by Wal-Mart/Sam's Club for approval to utilize automated will-call bin technology. The will-call bin/kiosk is designed to allow for controlled storage management, purchase and will-call pick-up of prescriptions during or after pharmacy hours. Mr. Fuller summarized concerns regarding compliance with patient counseling rules and pharmacy standards in the absence of a pharmacist, which does not permit prescriptions to be removed from the pharmacy without a pharmacist present.

Mr. Jason Reiser of Wal-Mart was accompanied by William Holmes, the vendor president. Mr. Reiser described the automated will-call bin as another deliver device; such as, mail order, courier, etc. Currently, the will-call bins are utilized in 15 states. Most recently, Nevada passed final rules on will-call/retail delivery devices.

### Automated Will-Call Bin - Specifications

- 7.5 feet tall and 600 – 800 lbs.
- Floor bolts and door locks.
- Holds up to 1000 prescriptions.
- Barcode verification during loading & delivery.
- Integrated with pharmacy computer system.
- Front & rear access.
- Full inventory.
- Electronic signature pad.
- Manual override for power outage.
- Telephone for contacting pharmacist after pharmacy hours.
- Customer has a user name and a personal identification issued – the PIN is only known to the person registering on the machine.
- If more than one Rx available, customer may select which Rx they purchase at that time.

- Machine asks for customer to verify medications with on-screen reference.
- Digital photograph and signature.
- 52 languages
- Options to customize configurations of screens

Use of the kiosk is optional for patients. The pharmacist will designate which 2<sup>nd</sup> or 3<sup>rd</sup> time refill prescription will be available for access through the kiosk. The selection will be done on a case by case basis and will include only refills where no counseling is deemed necessary. It is estimated that one-third of all refills processed at the pharmacy would be accessed by using the kiosk and only 5% of those prescriptions would be accessed after pharmacy hours.

Mr. Rieser demonstrated the operation of the will-call bin/kiosk and explained options that can be tailored based on the Board's requirements.

**MOTION:** Rosemarie Duffy moved that Wal-Mart/Sam's Club is directed to work with Board staff Tim Fuller and Grace Cheung in drafting a written proposal for review and approval by the Board prior to the initiation of a six-month pilot. The proposal shall include the following conditions:

1. Refills only, pass through front of kiosk.
2. The kiosk instructions provides the patient a 2<sup>nd</sup> opportunity to speak to pharmacist after the drug is delivered.
3. Will-call bin/Kiosk is physically attached to the pharmacy.
4. The kiosk has a telephone to allow patient to speak with a Washington licensed pharmacist.
5. The kiosk is operational only when the pharmacy is open.
6. Board Investigators will negotiate with Wal-Mart on placement of will-call bins/kiosks

Susan Teil-Boyer second. VOTE: 3 -3. Donna Dockter, Rosemarie Duffy and Susan Teil-Boyer voted in favor – George Roe, Gary Harris and Rebecca Hille voted in opposition. Chair Asaad Awan breaks tie in favor of motion. **MOTION CARRIED.**

### **EXECUTIVE SESSION – CLOSED SESSION**

The Board adjourned for Executive Session at 12:00 p.m. to discuss personnel issues and pending litigation.

The Board reconvened at 1:06 p.m.

Chair Awan announces that the Central Fill proposal by Rx.com has been postponed to a future meeting (Agenda Item 4.2). In addition, the Government Management Accountability & Performance video of the Health Professions' Oversight and Discipline presentation to Governor Gregoire was removed from the agenda (Item 4.3).

### **DISCUSSION Cont'd**

#### **Open Forum with WSU College of Pharmacy Students**

The open forum provided an opportunity to inform WSU College of Pharmacy 3<sup>rd</sup> year students on the role of the Board on the practice of pharmacy in Washington and its current activities. Issues and exchanges of information included intern/externship programs; pharmacists' licensing

requirements, jurisprudence examination, and NAPLEX; access to care (Pharmacists' Professional Responsibilities Rule), pharmacists' staffing issues; medication errors/safety; patient counseling; FDA – Plan B over-the-counter; Provider Look-up Website; statutes (RCW's) and administrative rules (WAC's); Uniformed Disciplinary Act and Washington Recovery Assistance Program for Pharmacy (WRAPP); household pharmaceutical return pilot (PH:ARM); and Collaborative Agreements.

The Board extends its thanks to the WSU College of Pharmacy faculty and students for their participation.

#### Delegation to Initiate Investigations.

Lisa Salmi lead the discussion regarding the August of 2005 Yoshinaka A & B decision and an opinion issued by the Washington State Court of Appeals that investigations could not proceed until the Board or Commission reviewed the complaint and determined that there was reasonable grounds to believe that unprofessional conduct had occurred.

However, the Court of Appeals acknowledged that Boards and Commissions did have the authority to adopt rules to allow delegation to staff to initiate an investigation. The Board was asked to consider rule making to delegate to staff the authority to investigate allegations of unprofessional conduct and applicants or credential holders who may be unable to practice with reasonable skill and safety by reason of mental or physical condition.

Proposal 1 – Delegates authority to a Case Management Team (CMT) which will include the Executive Director or designee, a pharmacist investigator, and staff attorney.

Proposal 2 – Delegate authority to a CMT which will include a Board member, the Executive Director or designee, a pharmacist investigator, and staff attorney.

The Board expressed interest in considering proposed draft 1 with amended language where established categories of unprofessional conduct may be delegated to CMT for initiation of investigations. Conduct not included in the established categories must be considered for investigation by CMT and a Board member. The Board did not enter a motion on this issue.

**ACTION:** Staff will developed a list of categories for the Board's review at a later date.

#### Suspicious Transaction Rule.

The Board discussed proposed rule language regarding reporting requirements for wholesale and retail suspicious sales or transfers of ephedrine, pseudoephedrine and phenylpropanolamine in excess of legitimate consumer needs.

**MOTION:** Rebecca Hille moved that the Board file a proposed rule language with the Office of the Code Reviser (CR102) with correction to subsection 4 removing the "s" to over-the-counter drugs. George Roe second. **MOTION CARRIED 6-0.**

#### Rule Prioritization.

The Board was asked to priorities rule making activities using the guidelines provided by the Department of Health and to name a Board member sponsor for each rule. The Department's guidance established priority criteria as 1) Legislative mandates 2) High priority and patient safety rules; 3) Petitions for rule making; and 4) Discretionary rules.



1. Pharmacist's Professional Responsibilities – All members
2. Sexual Misconduct – Donna Dockter
3. Precursor Suspicious Transaction –
4. Pharmacy Technicians' National Standardized Examination –
5. Extended Care Facilities Destruction of Controlled Substances – Asaad Awan
6. Add Soma to CSA – Gary Harris
7. Update Wholesaler Rules – Asaad Awan
8. Update Animal Control Agency and Humane Society Rules\* – Rosemarie Duffy
9. Stop Renumbering Refill Rx if No Changes are Made to the Original Prescription – Rebecca Hille
10. Extend Expiration of Non-Controlled Substance Prescription to 2 years – Rebecca Hille
11. Update Controlled Substance Act – George Roe
12. Update Hospital Rules – Susan Teil-Boyer, Asaad Awan
13. Law Book – Asaad Awan

\*Correction noted for petitioner - Update Animal Control Agency and Humane Society Rules – corrected to Adam Karp.

#### Multiple Prescriptions for Schedule II Drugs.

The Board reviewed the Drug Enforcement Agency's proposed regulations allowing authorized practitioners to issue multiple Schedule II prescription on the same day with instruction to fill on different dates allowing patient to receive up to a 90 day supply of controlled substances so long as specific conditions are met.

Andy Mecca summarized that the proposed rule would:

1. Allow an authorized practitioner to issue up to but not to exceed 90 days of multiple prescriptions – example- three prescriptions for 30 day supply.
2. Restrict pharmacists from filling the prescription prior to the date specified on the prescription.

Mr. Mecca reiterated that pharmacists may not change or add the patient's name, drug or physician's signature to a CII prescription. The dose, strength, and directions may be changes or added upon the permission of the prescriber.

**ACTION:**The Board has asked staff to write a letter to the DEA in support of the proposed rule regarding multiple prescriptions for CII's.

#### Correspondence

The Board was provided copies of the Governor's 1<sup>st</sup> Annual Government Accountability Report, and information regarding a performance audit of the Department of Health, Health Professions Quality Assurance office.

Gary Harris asked about the implications of the consolidation/realignment of the Health Systems Quality Assurance Division (HSQA) reference in the audit summary and how it may impact the personnel of Health Section 4. (In August 2006, Laurie Jenkins, Assistant Secretary of HSQA briefed the Board on the divisions realignment strategies.)

Lisa Salmi offered that the realignment is still in the planning stages. Recently, Department's staff were briefed on the process used to design the restructure of the Assistant Secretary's office to include new staff focused on human resources and media. The realignment of HSQA will impact the division as a whole; therefore, plans are to move forward with all offices simultaneously.

**ACTION:** George Roe, Rebecca Hille, and Asaad Awan will work with Lisa Salmi and Grace Cheung to write a letter to the Assistant Secretary expressing the effectiveness and efficiencies in preserving the education and experiential expertise of pharmacists when conducting investigations and inspections of pharmacy practice sites and disciplinary cases.

#### Consumer Waste Pharmaceutical Collection Pilot Program.

In August the Board approved the model guidelines to be used by pharmacies in developing their policies and procedures for participation in the Pharmaceuticals from Households: A Return Mechanism (PH:ARM) pilot. The Board was asked will consider delegating approval of these operating policies and procedures to staff.

Doug Beeman, representing Group Health Cooperative provided an update of the GHC participating pilot locations and indicated that all sites will be operational on Monday, October 30, 2006. Pilot locations include:

- Seattle Eastside Primary Care
- Olympia
- Silverdale
- Everett
- Renton
- Burien
- Spokane Riverfront

**ACTION:** Department staff is requested to coordinate with Department of Ecology to draft a media release announcing the PH:ARM pilot.

**MOTION:** Susan Teil-Boyer moved to delegate to staff the review and approval of policies and procedures submitted for participation in the Household Pharmaceutical Waste Pilot Project. Rebecca Hille second. **MOTION CARRIED 6-0.**

#### OPEN FORUM

Doug Beeman, Group Health Cooperative – shared new OTC packaging for Plan B.

Mr. Beeman also inquired to the status of the Executive Director appointment. Lisa Salmi explained that the position was offered to a candidate but he elected not to accept. The Department will begin recruitment in the near future. The Board acknowledged Lisa Salmi for her work as Acting Executive Director.

#### PRESENTATION OF AGREED ORDERS

#### Adjournment

There being no further business, the Board adjourned at 4:05 p.m. They will meet again on December 14, 2006 in Kent, Washington.

*Respectfully Submitted by:*

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*Doreen E. Beebe, Program Manager*

*Approved on December 14, 2006*

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*Dr. Asaad Awan, Chair  
Board of Pharmacy*